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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,751	09/28/2001	Allan S. Myerson	14690.006US	2977

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

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DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,751

Applicant(s)

MYERSON ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-23, 25-42, 44 and 45 is/are rejected.
- 7) ☒ Claim(s) 8, 24, and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 6) ☐ Other: _____

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1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

There is no copendency between the instant application and application no. 09/348,200, which became abandoned on November 8, 2000.

The status of the applications referred to in the priority claim should be updated.

Correction is required.

2. The disclosure is objected to because of the following informalities: At page 2, line 11, it is possible that "or" should instead be "of". At page 5, line 31, "filed" should be changed to "field". The elements labeled 5-12, 14, 15, 20, 30, and 40 in Figure 1 are not described anywhere in the specification, such as in the detailed description of Figure 1. Appropriate correction is required.

3. Claims 14-17 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the laser light" in claims 14 and 17. Note that independent claim 1, upon which claims 14 and 17 depend, does not require the light to be laser light. There is no antecedent basis in the claims for the phrase "the solvent" at claim 37, line 1. It is believed that claim 37 should instead depend upon claim 36.

4. Claim 24 is objected to because of the following informalities: At claim 24, line 1, "of" is misspelled. Appropriate correction is required.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3-7, and 9-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,426,406.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '406 patent anticipate instant claims 1, 3, and 9-18. With respect to instant claims 4-7, while the '406 patent does not claim a particular wavelength or polarization, the '406 patent does claim selecting a wavelength and polarization state. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal wavelengths and polarization states for the claimed method of the '406 patent because the '406 patent claims the step of selecting these process variables and because it is prima facie obvious to determine and optimize all art-recognized result-effective variables.

7. Claims 1, 3-7, 9, and 11-18 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 09/918,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '935 application anticipate instant claims 1, 3, 4, 6, 7, 9, and 11-18. With respect to instant claim 5, while the '935 application does not claim a laser wavelength of 1064 nm, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal near infrared wavelengths for the claimed method

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of the '935 application, because the '935 application claims the step of selecting a wavelength and because it is prima facie obvious to determine and optimize all art-recognized result-effective variables.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 5-7 and 15 are directed to an invention not patentably distinct from claims 1-33 of commonly assigned copending Application No. 09/918,935. Specifically, see the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 09/918,935, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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9. The effective filing date of instant claims 1, 3, 4, 9-14, and 16-18 is deemed to be October 23, 2000, the filing date of parent application 09/694,404. Instant claims are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '404 parent application because the '404 parent application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

The effective filing date of instant claims 2, 5-8, 15, and 19-45 is deemed to be September 28, 2001, the filing date of parent application 09/694,404. Instant claims are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '404 parent application because the '404 parent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the specific aging time range of 1 hour to 200 hours, does not disclose the specific wavelength of 1064 nm, does not disclose light with linear, circular, or elliptical polarization, does not disclose the specific pulse rate range of between 1 and 100 pulses per second, and does not disclose the specific power range of between 0.1 and 10 GW/cm²)

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

11. Claims 1-4, 11-19, and 25-38 are rejected under 35 U.S.C. 102(b) as being anticipated by the Garetz et al article. The Garetz et al article teaches subjecting a supersaturated aqueous solution of urea which have been aged for one to two weeks (168 to 336 hours) to 1.06 μm wavelength, plane-polarized pulses from a Q-switched Nd:YAG laser to induce crystallization of the urea. The supersaturated solution was prepared by first heating and then cooling the urea solution. The power was 0.02 J with the oscillator alone, and 0.1J with the amplifier. The pulse rate was 10 pps, and nucleation typically occurred within 10-20 seconds. Light intensities were 50 and 250 MW/cm^2 (0.05 and .250 GW/cm^2). The solution is transparent to the laser light, i.e.

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does not absorb the laser light. Needle-shaped crystals are formed, which correspond to the polymorph required to be formed by Applicants' claims. The crystals that initially form tend to be aligned parallel to the electric field vector of the light, i.e. are a polymorph different than the polymorph that would spontaneously nucleate in the absence of the light selected. See, e.g., the Abstract and page 3475. Urea is an amine.

12. Claims 13 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by the Garetz et al article as applied against claims 1-4, 11-19, and 25-38 above, and further in view of the Merck Index. The Merck Index teaches that the urea of the Garetz et al article inherently is a pharmaceutical, e.g. a diuretic, and inherently is a derivative of a protein, i.e. is a product of protein metabolism.

13. Claims 2, 5, 10, 19-21, 25-39, and 45 are rejected under 35 U.S.C. 103(a) as being obvious over the Garetz et al article. Application of the Garetz et al article is the same as in the above rejection of claims 1-4, 11-19, and 25-38. To the extent that the Garetz et al article does not teach Applicants' claimed aging times, and light wavelengths, It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal aging times and light wavelengths because the Garetz et al article teaches that aging times and light wavelengths are art-recognized result-effective variables and it is routine and prima facie obvious to one of ordinary skill in the art to determine and optimize art-recognized result-effective variables. With respect to instant claims 10 and 45, while the Garetz et al article does not teach using its urea crystals as seed crystals, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the crystals of the Garetz et al article as seed crystals to form larger amounts of the urea polymorph because it is

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well-known in the crystallization art to use seed crystals to form larger amounts of polymorphs of the same substance, and because it is prima facie obvious to use the product of one known process as the reactant in a second known process. See *In re Kamlet*, 88 USPQ 106 (CCPA 1950).

14. Claims 1, 4, 9, 11-14, and 17 are rejected under 35 U.S.C. 102(a) and claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Blanks. Blanks teaches subjecting a supersaturated aqueous solution of sodium aluminate to about 0.8-4 micron wavelength linearly polarized pulses from a near-IR laser to induce precipitation of alumina hydrate, especially aluminum trihydrate. The supersaturated solution is prepared by the Bayer process and comprises the step of solvent evaporation by flashing. The power can be about 500 to 700 milliwatts. Exemplified treatment times are 15 and 30 minutes. Hexagonal single crystal gibbsite with diameters of typically 15-20 microns are formed, which correspond to the polymorph required to be formed by Applicants' claims, and which are not formed by Bayer processes which do not use the seedless laser treatment. See, e.g., the Abstract; column 1, lines 21-40; column 4, lines 23-28; column 5, lines 36-44; column 6, lines 29-43; column 9, lines 46-48; column 10, lines 22-23; column 11, lines 29-41; column 12, lines 16-17; and the claims.

15. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Blanks as applied against claims 1, 4, 9, 11-14, and 17 above, and further in view of the Merck Index. The Merck Index shows that the aluminum trihydrate precipitated by Blanks is a pharmaceutical, e.g., an antacid.

16. Claims 10, 15, 16, and 18 are rejected under 35 U.S.C. 103(a) as being obvious over Blanks. Application of Blanks is the same as in the above rejection of claims 1, 4, 9, 11-14, and

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17. Blanks does not teach using its gibbsite as seed crystals. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the gibbsite of Blanks as seed crystals to form larger amounts of the gibbsite because it is well-known in the crystallization art to use seed crystals to form larger amounts of polymorphs of the same substance, and because it is prima facie obvious to use the product of one known process as the reactant in a second known process. See *In re Kamlet*, 88 USPQ 106 (CCPA 1950). Blanks teaches that the laser is to be pulsed for a period of time, but does not teach a pulse rate or a laser treatment time in the range of 0.01 to 60 seconds. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal pulse rates and laser treatment times for the pulsed laser of Blanks because pulse rate is an art-recognized result-effective variable which is routinely determined and optimized in the pulsed laser arts, and because reaction time is an art-recognized result-effective variable which is routinely determined and optimized in the chemical arts.

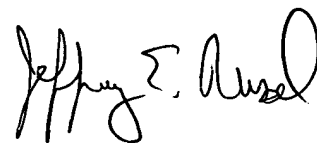
17. Claims 2, 5-7, 15, 19-23, 25-42, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Myerson (U.S. Publication No. 2003/0024470). Myerson teaches preparing supersaturated protein solutions by a combination of heating and cooling, aging the supersaturated protein solutions, and then treating the aged protein solutions with polarized laser light having a wavelength of 1064 nm and pulse rate of 10 pulses per second. The solvent can be water. Polarization can be linear or circular, the laser power can be 0.7 GW/cm^2 , and laser treatment time can range from 0.01 to 60 seconds. Aging can last for as little as 48 hours. See e.g., paragraphs 0040, 0046, 0058, 0059, and 0064.

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18. Claims 8, 24, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest crystallization from supersaturated solutions in the presence of light which is elliptically polarized. The references applied above are limited in their types of polarizations, and do not provide any motivation or suggestion to use elliptical polarization.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

March 10, 2003